

## REMARKS

Reconsideration of this application is respectfully requested.

New claims 120-224 have been added to replace the previously pending claims 34-119. New claims essentially correspond to cancelled claims while addressing several points made by the Examiner. For the Examiner's convenience, Applicants attach a table showing the correspondence between the cancelled and new claims (*see* Attachment I).

Support for the new claims is found throughout the specification and in the originally filed claims, such as, for example, in those portions of the specification that disclose the compounds of the invention and their uses, alone or in combination with other compounds (e.g. cyclooxygenase inhibitor), special use carriers, *i.e.*, pharmaceutical, veterinary and nutritional (food and dietary supplement), and/or instructions for use. *See inter alia*, page 3, line 27-page 4, line 7; page 5, lines 8-15; page 7, line 10-15, page 13, lines 13-15, and the text of the parent application U.S. Ser. No. 08/631,661 ["the '661 application"], initially incorporated by reference in the present application, and then inserted into the present application by the amendment filed March 28, 2001 pursuant to MPEP §§ 608.01(p) and 2163.07(b).

As to claims 123, 124, 135, 136, 147, 148, 156, 157, 165, 166, 174, 175, 184, 185, 189, 190, 197, 198, 208, 209, 220, and 221, they have been added to more fully claim that what Applicants regard as their invention. These claims additionally recite cocoa extracts, fractions thereof, and/or epicatechin and epicatechin containing oligomers and find support through out the specification, for example, page 7, lines 16-17, page 11, line 15, and the Examples.

Thus, no new matter has been added.

### **Status of Official Action**

The text of the Official Action at page 6, first full paragraph, indicates that this is a final official action. However, in view of: (i) the form PTO-326, which indicated that the Action is non-final and (ii) the telephone communication from the Examiner, Applicants believe that the statement as to the finality of Office Action on page 6 is an inadvertent error.

As the undersigned attorney has explained to the Examiner, a Request for Continued Examination of this application was filed on September 10, 2001, to avoid the extension of time

fees, with an intention to file a Supplemental Information Disclosure Statement shortly thereafter. However, due to the tragic events of September 11, Applicants were unable to file the Supplemental IDS on time for it to be considered by the Examiner. As suggested by the Examiner, this IDS is enclosed with the present response. Consideration of references cited therein is respectfully requested.

### **Rejection Under 35 USC § 112**

Claims 34-119 stand rejected under 35 U.S.C. Section 112, 1<sup>st</sup> par. on the ground that the specification, as originally filed, lacks support for the terms: aspirin, heart attack, stroke and hypertension. Applicants respectfully point the Examiner to the following pages of the specification which contain support for these terms.

For example, page 3, line 2 (as amended pursuant to MPEP §§ 608.01(p) and 2163.07(b)) discloses a combination of cocoa procyanidins and a cyclo-oxygenase (COX) inhibitor and page 15, lines 5-7 discloses aspirin as a COX inhibitor. The amended text is from the patent '661 application, which is incorporated by reference in the present application; thus, the claims reciting cyclo-oxygenase modulators, non-steroidal inflammatory drugs and aspirin are also supported by the disclosure of the '661 parent application.

Support for the terms heart attack, stroke and hypertension is found in the disclosure of Figure 2; and at page 11, line 25 to page 12, line 2; page 16, line 21 to page 18, line 11. The parent '245 application also provides support for these terms, for example, at page 46, line 4 to page 50, line 2; and page 53, lines 5 to page 55.

Therefore, the withdrawal of the rejection is respectfully requested.

Claims 102 and 111 stand rejected for lack of written description and as indefinite on the ground that the specification does not define the phrases "preventing conditions associated with inflammatory diseases" and "preventing conditions associated with inflammation". The Examiner states that the specific diseases must be disclosed in the specification to enable the Examiner to determine if such diseases are preventable. Claims 102-117 have been canceled. Applicants note however that claims 102-110 did not recite "preventing conditions associated with inflammatory diseases." As to new claims 216-224 that correspond to canceled claims 111-117, the rejection is respectfully traversed for the reasons outlined below.

The Applicants are not aware of any legal precedent requiring that each term or phrase utilized in the claims be defined in the specification. In fact, the terms that would be understood by those skilled in the art in light of the specification and the general knowledge in the art need not be defined. Applicants submit that, in view of the art recognized meaning of the term "inflammation," and the underlying mechanisms and exemplary diseases disclosed in the specification, a person of skill in the art would understand the meaning of the phrase "inflammatory condition" recited in claims 216-224 and what conditions were in possession of Applicants as of the filing date. However, in order to expedite the prosecution of the application, and since the rejection appears to be imposed because of the recitation of disease *prevention*, claim 216-224 do not recite a method of prevention. Withdrawal of the rejections is, therefore, respectfully requested.

Claims 39, 49, 59, 66, 73, 86, 98 and 107 stand rejected as indefinite on the ground that the specification does not define the phrase "food science carrier. Applicants respectfully submit that a person of skill in the art would understand the meaning of the term food science carrier based on the disclosures of the specification. However, in order to expedite the prosecution of the application, the objected to terminology has been eliminated from new claims 127, 139, 151, 160, 169, 178, 193, 201, 212 and 224. Withdrawal of the rejections is, therefore, respectfully requested.

Composition claims stand rejected as indefinite for reciting only one component. New claims further recite "a carrier selected from the group consisting of a pharmaceutically acceptable carrier, veterinary acceptable carrier, dietary supplement carrier and food." It is believed that the rejection is obviated.

Claims 79-81 were rejected for reciting "modulating nitric oxide" and claims 118 for reciting "inhibiting lipoxxygenase activity" on the ground that they are indefinite for failing to recite a treatment method. New claims do not contain these phrases.

As to the rejection of claims 93-101 on the ground that "a method of anti-platelet therapy" is indefinite, Applicants respectfully traverse this rejection as to new claims 194-204. The term "anti-platelet therapy" is well known in the art as shown in the attached article bearing the same title. Withdrawal of the rejection is respectfully requested.

In view of the new claims and the above remarks, Applicants believe that all Section 112, 1<sup>st</sup> and 2<sup>nd</sup> par., rejections were overcome. Withdrawal of the rejections is respectfully requested.

**Rejection Under 35 USC § 102**

Claims 34-40 and 44-78 stand rejected under 35 USC § 102(b) as anticipated by Clapperton *et al.*, on the ground that the reference teaches compositions containing cocoa procyanidins.

Claims 34-40 and 44-78 have been cancelled. The rejection is addressed with respect to new claims 120-128 and 132-185, which correspond to the cancelled claims. The packaged compositions of claims 120-128, 132-140, and 144-179 are not disclosed by Clapperton. The claims call for (i) a composition comprising cocoa procyanidin(s) and a pharmaceutical, veterinary, dietary supplement or food carrier and (ii) instructions for use packaged together with the composition. There is no disclosure in Clapperton *et al.* of combining cocoa procyanidins with any of the recited carriers and/or with instructions for use to produce a packaged composition of claims 120-128, 132-140, and 144-179. In fact, the Examiner has acknowledged this distinction at page 6, first par., of the Official Action.

Claims 141-143 and 180-185 call for the combination of cocoa procyanidin monomer and/or oligomer and a cyclo-oxygenase modulating compound (e.g. aspirin). Since the Examiner did not reject claims 129-131, which also recite this combination, Applicants believe that the rejection of claims 141-143 and 180-185 was inadvertent. Clapperton fails to disclose cyclo-oxygenase modulating compounds.

Therefore, the withdrawal of the rejection is believed to be in order. Such action is respectfully requested.

**Rejection Under 35 USC § 103**

Claims 34-40 and 44-78 stand rejected under 35 USC § 103 as obvious over Clapperton *et al.*, on the ground that “being in packages having instructions for use is not in and of itself patentable over the prior art of Clapperton” (Official Action, page 6, first par.). Applicants respectfully traverse the rejection with respect to new claims 120-128 and 132-183.

Clapperton *et al.* were concerned with astringency (bitterness) of cocoa beans and their results teach nothing but that "[p]rocyanidins [are] the principal class of compounds responsible for the astringency of cocoa beans and liquor" (*see* page 4, under "Conclusions"). There is no teaching or suggestion of any utility of these compounds. Without such a suggestion, a person of skill in the art would not have been motivated to manufacture compositions containing cocoa procyanidin monomer and/or oligomer in combination with a pharmaceutical, veterinary, dietary supplement or food carrier, and to package the composition with instructions for use. Particularly there is no suggestion of the health benefits recited in rejected claims.

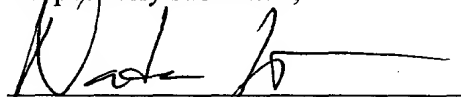
Accordingly, withdrawal of the rejection is believed to be in order. Such action is respectfully requested.

**Conclusion**

The application is believed to be in conditions for allowance. An action to this effect is respectfully requested.

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Respectfully submitted,



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